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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
RAMIREZ,D	
ART UNIT	**PAPER NUMBER**
1652	7

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/606,129	Applicant(s) MAINES, MAHIN D.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Status of Application

Claims 1-67 are pending. The Information Disclosure Statement filed on 8/21/2000 is acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method for regulating protein kinase activity, classified in class 435, subclass 25.

II. Claims 10-20, drawn to a method for regulating cell differentiation, growth, or signaling, classified in class 435, subclass 25.

III. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for diabetes mellitus, classified in class 435, subclass 25.

IV. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for ischemia, classified in class 435, subclass 25.

V. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for inflammation, classified in class 435, subclass 25.

VI. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or

diseased cell responsible for central nervous system disorders, classified in class 435, subclass 25.

VII. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for cardiovascular disease, classified in class 435, subclass 25.

VIII. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for Alzheimer's disease, classified in class 435, subclass 25.

IX. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for dermatological disease, classified in class 435, subclass 25.

X. Claims 21-37, drawn in part to a method for treating a cellular dysfunction or disease comprising contacting biliverdin reductase with a dysfunctional or diseased cell responsible for cancer, classified in class 435, subclass 25.

XI. Claims 38-46, drawn to a method for treating cells following a stroke, classified in class 435, subclass 25.

XII. Claims 47-57, drawn to a biliverdin reductase, classified in class 435, subclass 189.

XIII. Claims 58-66, drawn to a vector and host cell comprising a DNA molecule encoding a biliverdin reductase, classified in class 435, subclass 320.1.

XIV. Claim 67, drawn to an antibody against biliverdin reductase or a fragment thereof, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions XII and I, II, III, IV, V, VI, VII, VIII, IX, X, or XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention XII can be used in the patentably distinct methods of Inventions I, II, III, IV, V, VI, VII, VIII, IX, X, or XI.

Inventions XIII and II, III, IV, V, VI, VII, VIII, IX, or X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vector of Invention XIII can be used in the patentably distinct methods of Inventions II, III, IV, V, VI, VII, VIII, IX, or X.

Groups XII, XIII, and XIV each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The vector in Group XIII comprises a nucleic acid sequence whereas the proteins of Groups XII and XIV each comprise an unrelated amino acid

sequence. The nucleic acid has other uses besides encoding for the protein of Group XII such as a hybridization probe or in gene therapy. The protein from Group XII can be used in materially different methods other than to make the antibody of Group XIV, such as in therapeutic or diagnostic methods (e.g. screening). Further, the proteins of Groups XII and XIV can be prepared by processes which are materially different from recombinant DNA expression of Group XIII, such as by chemical synthesis, or by isolation from natural sources.

Inventions XIV and I, II, III, IV, V, VI, VII, VIII, IX, X, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Invention XIV is neither used nor made by the patentably distinct methods of Inventions I, II, III, IV, V, VI, VII, VIII, IX, X, or XI.

Inventions XIII and I, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the vector of Invention XIII is neither used nor made by the patentably distinct methods of Inventions I or XI.

Inventions I and II, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions I, II, or XI are not disclosed as capable of use together, each comprise different steps, utilize different products in addition to biliverdin reductase, and produce different results.

Inventions III-X are related by virtue of being methods for treating a cellular dysfunction or disease using biliverdin reductase. However they are patentably distinct inventions because the targets of biliverdin reductase in diabetes mellitus, ischemia, inflammation, central nervous system disorders, cardiovascular disease, Alzheimer's disease, dermatological disease, and cancer are different dysfunctional or diseased cells, therefore the conditions required for effective contact and treatment for each disease are not expected to be the same. A search and examination of the targets for biliverdin reductase in diabetes mellitus, ischemia, inflammation, central nervous system disorders, cardiovascular disease, Alzheimer's disease, dermatological disease, and cancer would result in an undue burden, since the searches are not co-extensive and the subject matter divergent.

Inventions I and III-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions I and III-X are not disclosed as capable of use together, each comprise different steps, utilize different products in addition to biliverdin reductase, and produce different results.

Inventions II and III-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions II and III-X are not disclosed as capable of use together, each comprise different steps, utilize different products in addition to biliverdin reductase, and produce different results.

Inventions XI and III-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions XI and III-X are not disclosed as capable of use together, each comprise different steps, utilize different products in addition to biliverdin reductase, and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
September 17, 2001

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

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September 17, 2001